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PATENT
ATTORNEY DOCKET NO.: JHU1630

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Sukumar et al. Art Unit: Unassigned
Application No.: 09/771,357 Examiner: Unassigned
Filed: January 26, 2001
Title: ABERRANTLY METHYLATED GENES AS MARKERS OF BREAST
MALIGNANCY

Commissioner for Patents
Washington, D.C. 20231

INFORMATION DISCLOSURE STATEMENT

Sir:

In accordance with 37 C.F.R. § 1.97, enclosed are references relating to the above-identified application. For the convenience of the Examiner, these references are listed on the attached Form PTO-1449 and a copy of each is enclosed herewith.

It is respectfully requested that these references be considered in the examination of this application and their consideration be made of written record in the application file.

| CERTIFICATION UNDER 37 CFR §1.8 | |
|--|-----------------------|
| I hereby certify that the documents referred to as enclosed herein are being deposited with the United States Postal Service as first class mail on this date, April 26, 2001 , in an envelope addressed to: Commissioner for Patents, Washington, D.C. 20231. | |
| Cecilia Tobin | |
| Name of Person Mailing Paper | |
| <i>Cecilia Tobin</i> | April 26, 2001 |
| Signature | Date |

In re Application of:
Sukumar et al.
Application No.: 09/771,357
Filed: January 26, 2001
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PATENT
Attorney Docket No.: JHU1630

No fee is deemed necessary in connection with the filing of this Information Disclosure Statement, because it is being filed prior to the receipt of a first office action on the merits of the above-captioned application. However, if any fee is required, authorization is hereby given charge any fees associated with the filings submitted herewith, or credit any overpayment to Deposit Account No. 50-1355. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

Date: April 26, 2001



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TRANSMITTAL SHEET

Sir:

Transmitted herewith for the above-identified application please find:

1. Information Disclosure Statement (2 pages);
2. Form PTO-1449 (2 pages);
3. Three (3) U.S. Patent Documents;
4. Eight (8) Other Documents; and
5. Return Receipt Postcard.

| CERTIFICATION UNDER 37 CFR §1.8 | |
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| I hereby certify that the documents referred to as enclosed herein are being deposited with the United States Postal Service as first class mail on this date, April 26, 2001 , in an envelope addressed to: Commissioner for Patents, Washington, D.C. 20231. | |
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| (Name of Person Mailing Paper) | |
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USPTO Customer Number 28213

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| FORM PTO-1449 U.S. Department of Commerce Patent and Trademark Office | Docket No. (Optional) JHU1630 | Application No.: 09/771,357 |
| | Applicants: Sukumar et | |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT | Filing Date: January 26, 2001 | Group Art Unit: Unassigned |

U.S. PATENT DOCUMENTS

| EXAM. INITIALS | | DOCUMENT NUMBER | DATE | NAME | CLASS | SUB-CLASS | FILING DATE |
|----------------|----|-----------------|----------|---------------|-------|-----------|-------------|
| | AA | 5,786,146 | 07/28/98 | Herman et al. | | | |
| | AB | 6,017,704 | 01/25/00 | Herman et al. | | | |
| | AC | 6,200,756 B1 | 03/13/01 | Herman et al. | | | |

FOREIGN PATENT DOCUMENTS

| EXAM. INITIALS | | DOCUMENT NUMBER | DATE | COUNTRY | CLASS | SUB-CLASS | TRANSLATION (YES/NO) |
|----------------|--|-----------------|------|---------|-------|-----------|----------------------|
| | | NONE | | | | | |

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages)

| | | |
|--|----|--|
| | AD | Baylin and Herman, "DNA hypermethylation in tumorigenesis," <i>TIG</i> 16 (4) :168-174 (2000) |
| | AE | Ferguson, et al., "High frequency of hypermethylation at the 14-3-3 σ locus leads to gene silencing in breast cancer," <i>PNAS</i> 97 (11) :6049-6054 (2000) |
| | AF | Ferguson, et al., "Demethylation of the Estrogen Receptor Gene in Estrogen Receptor-negative Breast Cancer Cells Can Reactivate Estrogen Receptor Gene Expression," <i>Cancer Research</i> 55 :2279-2283 (1995) |
| | AG | Nass, et al., "Aberrant Methylation of the Estrogen Receptor and E-Cadherin 5' CpG Islands Increases with Malignant Progression in Human Breast Cancer," <i>Cancer Research</i> 60 :4346-4348 (2000) |

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| EXAMINER | DATE CONSIDERED |
|----------|-----------------|

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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|---|---|---------------------------------------|
| FORM PTO-1449 U.S. Department of Commerce Patent and Trademark Office | Docket No. (Optional) JHU1630 | Application No.: 09/771,357 |
| | Applicants: Sukumal et al. | |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT | Filing Date: January 26, 2001 | Group Art Unit: Unassigned |

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|--|----|--|
| | AH | Ottaviano, et al., "Methylation of the Estrogen Receptor Gene CpG Island Marks Loss of Estrogen Receptor Expression in Human Breast Cancer Cell," <i>Cancer Research</i> 54 :2552-2555 (1994) |
| | AI | Raman, et al., "Compromised HOXA5 function can limit p53 expression in human breast tumours," <i>Nature</i> 405 :974-976 (2000) |
| | AJ | Raman, et al., "HOXA5 Regulates Expression of the Progesterone Receptor," <i>The Journal of Biological Chemistry</i> 275 (34):26551-2655 (2000) |
| | AK | Sirchia, et al., "Evidence of epigenetic changes affecting the chromatin state of the retinoic acid receptor β 2 promoter in breast cancer cells," <i>Oncogene</i> 19 :1556-1563 (2000) |

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